REMARKS

Applicant has carefully studied the outstanding Official Action mailed on March 4, 2008. This response is intended to be fully responsive to all points of rejection raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application are respectfully requested.

Claims 1 and 5-15 (*sic*, claim 11 has been canceled previously) stand rejected under 35 USC §103(a) as being unpatentable over Shain et al (US 6027349), Douglas et al (US 5951492), Moerman et al (US 6706159) or Stiene et al. (US 2004/0096959) in view of Eason et al (5186897) alone or further in view of Tenerz et al (US 4941473).

The Examiner states in his rejection:

These references are silent to configuration of a first optical waveguide in a first housing is connected to a second optical waveguide to effect communication between the processor and said optical sensor. Additionally, these references are silent to the claimed "destructive fluids for neutralizing substances".

Eason et al. teach in columns 2-3 lines 15-7 respectively teaches optical waveguides are advantageous because they eliminate the need to separate and wash the sample.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable results. It is well know in the art to connect a waveguide with the processor by a waveguide. Further, it is well known when testing biological sample, it is desirable to make the portion of the test device in contact with the sample disposable to minimize the opportunity of contamination to the equipment or user. The selection of the connection of a waveguide to the processor is a result effective variable having the well known and expected results of providing a signal representative of the sample to the processor.

It would have been within the skill of the art to modify Shain et al. (USP 6,027,349), Douglas et al. (USP 5,951,492), Moerman et al. (USP 6,706,159) or Stiene

et al. (2004/0096959) in view of Eason et al. and use an optical waveguide having a first portion that is in contact with the biological sample connected to a second portion that is in contact with the processor as optimization of a result effective variable and to gain the above advantages.

Applicant respectfully traverses these rejections. The optical waveguide in Eason et al. is used in a different manner than the instant invention.

Eason et al. uses an optical waveguide with one portion coated with a ligand and another portion coated with a dissoluble fluorescent reagent which has affinity for the ligand. A sample is drawn into the waveguide and a reaction occurs with the ligand and the reagent. Due to evanescent wave coupling, the intensity of fluorescence caused by the reaction can be measured to assess the quantity of reagent bound to the waveguide and thus measure the amount of analyte in the sample.

The above is clearly stated in columns 2-3 lines 15-7 of Eason et al., which was cited by the Examiner (emphasis added by underlining):

"Recently, an optical biosensor for immunoassays, the fluorescence capillary-fill device (FCFD) has been proposed. The device is based on an adaptation of the technology used to mass manufacture liquid-crystal display (LCD) cells. The device uses the principles of optical fibres and waveguides to reduce the need for operator attention and it avoids the need for physical separation methods or washing steps in the assay. An FCFD cell typically comprises two pieces of glass which are separated by a narrow gap. One piece of glass is coated with a ligand and acts as a waveguide. The other piece is coated with a dissoluble fluorescent reagent which has affinity for the ligand (in competition assays) or the analyte (in non-competitive labelling assays). When a sample is presented to one end of the FCFD cell it is drawn into the gap by capillary action and dissolves the reagent. In a competitive assay the reagent and analyte compete to bind to the ligand on the waveguide and the amount of bound reagent is inversely proportional to the concentration of analyte. In an immunometric assay, the amount of reagent which becomes bound to the waveguide is directly proportional to the amount of analyte in the sample. As the gap between the pieces of glass is narrow (typically 0.1 mm) the reaction will usually go to completion in a short time, probably in less than 5 minutes in the case of a competition assay.

FCFD cells avoid the need for separation steps and/or washing steps by using an optical phenomenon known as evanescent wave coupling. Basically, the fluorescence from unbound reagent molecules in solution enters the waveguide which comprises the baseplate

of the FCFD at relatively large angles (e.g. more than 44.degree. for a serum sample) relative to the plane of the waveguide and emerge from the waveguide at the same large angles in accordance with Snell's Law of Refraction. On the other hand, reagent molecules bound to the surface of the waveguide emit light into all angles within the waveguide. By measuring the intensity of fluorescence at smaller angles to the axis of the guide (e.g. less than 44.degree. for a serum sample), it is possible to assess the quantity of reagent bound to the surface thereby allowing the amount of analyte in the sample to be measured. The principles involved in FCFDs are described in more detail in U.S. Pat. No. 4,978,503.

As mentioned earlier the ligand bound to the waveguide is selected to suit the FCFD to a particular assay. Also, FCFDs allow for rapid tests without the need for accurate measurement of sample or reagent(s) and without the need for separation and washing steps. These factors suggest that FCFDs will be useful in simplifying multianalyte test apparatus. However, there is a need to provide an arrangement whereby the timing of the contact of sample with the FCFDs is controlled, since timing is important in rapid assays, and where the various FCFDs can be brought into alignment with both the light source acting as the fluorescence pump and the fluorescence detector which needs to be aligned with the end of the waveguide. Moreover, there is a need to avoid contamination of the optical surfaces of the FCFDs by stray sample or other matter which would affect optical quality."

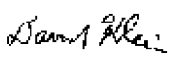
Please note that Eason et al. does not teach using an optical waveguide to optically connect the optical sensor to the processor. Instead, Eason et al. teaches using the optical waveguide as the place where the reaction takes place and uses an external fluorescence measuring device to measure the fluorescence created in the optical waveguide. The fluorescence measuring device is not connected to the optical waveguide.

In contrast, in the present invention, the optical waveguides optically connect the optical sensor to the processor. This is entirely different from Eason et al. Thus the combination of Shain et al., Douglas et al., Moerman et al. or Stiene et al. in view of Eason et al. alone (and certainly further in view of Tenerz et al.) cannot and does not anticipate or make the instant invention unpatentable.

Claims 16-19 have been added and are also deemed patentable over the art.

Accordingly, claims 1, 5-10 and 12-19 are respectfully deemed allowable. Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,
DEKEL PATENT LTD.



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